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January 18, 2002

Dockets Management Branch
Food and Drug Administration
Room 1061
5630 Fishers Lane (HFA-305)
Rockville, MD 20852

Petition for Reconsideration: D.C. #K010952

The undersigned submits this petition for reconsideration of the decision of the Commissioner of Food and Drugs in D.C. #K010952.

A. Decision involved

On December 19, 2001, FDA determined that the 510(k) premarket notification for the SURGISIS™ Periodontal Membrane (D.C. #K010952) could not be evaluated for substantial equivalence without clinical data demonstrating efficacy for the indications to be cleared and resorption characteristics of the device.

B. Action requested

The petitioner requests that the Commissioner, or his designee, find the data in the administrative record to be sufficient for determining and for demonstrating substantial equivalence of the SURGISIS™ Periodontal Membrane (D.C. #K010952) to legally marketed predicate devices.

C. Statement of grounds

The history of communications¹ regarding the above named device culminated in a telephone conference between FDA and Company representatives. This conference concluded with agreement that the device could be reviewed for substantial equivalence without clinical data if resorption data were provided and no specific effectiveness claims were sought. The Company agreed with this conclusion because substantial equivalence of function as a membrane may be demonstrated with non-clinical testing, and no new

¹ Mar 29, 2001 original 510(k) premarket notification submitted
Jun 25, 2001 FDA request for additional information for review of submission
Jul 24, 2001 additional information submitted with request for telephone conference
Oct 9, 2001 a proposed agenda and background information were provided to FDA
Oct 23, 2001 telephone conference held, 510(k) placed on hold
Oct 29, 2001 telephone conference notes submitted
Nov 19, 2001 additional information characterizing resorption provided to FDA
Dec 19, 2001 510(k) found deficient and withdrawn

02 P-0045

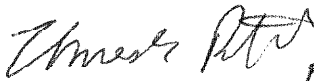
PRC 1

questions of safety or effectiveness appeared to be raised. The claims and data were submitted as agreed, but the review was not completed, resulting instead in a stated requirement for clinical data and withdrawal of the premarket notification. The fact that the reviewer who participated in the telephone conference was not available and did not review the additional material may have contributed to the unexpected outcome. It is also worth noting that no comments regarding the telephone conference notes were provided by FDA.

It is our belief that the relevant information in the administrative record was not adequately considered and that the action requested is not frivolous, is sought in good faith, is consistent with sound public policy, and is not outweighed by public health interests.

Thank you for your consideration of this request.

Sincerely,

 For Mark Bleyer

Mark Bleyer
President

MB:tw
Enclosures

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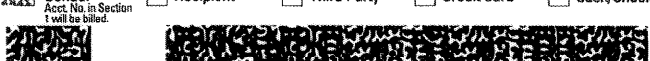
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